

§ 520.445c

21 CFR Ch. I (4–1–02 Edition)

Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount*. 200 to 400 milligrams per gallon.

(1) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae*.

(2) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(B) *Amount*. 400 to 800 milligrams per gallon.

(1) *Indications for use*. Control of chronic respiratory disease and air-sac infections caused by *M. gallisepticum* and *E. coli*.

(2) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(C) *Amount*. One thousand milligrams per gallon.

(1) *Indications for use*. Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(2) *Limitations*. See paragraph (d)(4)(i)(A)(2) of this section.

(ii) *Growing turkeys*—(A) *Amount*. 400 milligrams per gallon.

(1) *Indications for use*. Control of infectious synovitis caused by *M. synoviae*.

(2) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(B) *Amount*. 25 milligrams per pound of body weight daily.

(1) *Indications for use*. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

(2) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(iii) *Swine*—(A) *Amount*. 10 milligrams per pound body weight daily in divided doses.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days; for 000010 and 017519 do not slaughter animals for food within 5 days of treatment; for 010042 do not slaughter animals for food within 24 hours of treatment.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 milligrams per pound daily in divided doses.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations*. Prepare fresh solution daily; use as a drench; as sole source of chlortetracycline; do not use for more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not use in lactating cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal.

[57 FR 37324, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 61015, Nov. 19, 1993; 59 FR 39439, Aug. 3, 1994; 60 FR 26827, May 19, 1995; 60 FR 47052, Sept. 11, 1995; 62 FR 27691, May 21, 1997; 62 FR 35076, June 30, 1997; 62 FR 60656, Nov. 12, 1997; 64 FR 37673, July 13, 1999; 65 FR 10706, Feb. 29, 2000; 66 FR 35898, July 10, 2001]

§ 520.445c Chlortetracycline tablets and boluses.

(a) *Specifications*. Each tablet/bolus contains 25, 250, or 500 milligrams of chlortetracycline hydrochloride.

(b) *Sponsors*. See No. 000010 in § 510.600(c) of this chapter for the 250-milligram chlortetracycline hydrochloride bolus; see No. 010042 for the 25-milligram tablet and the 500 milligram bolus.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *National Academy of Sciences/National Research Council NAS/NRC status.* The conditions of use specified in this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(e) *Conditions of use. Calves*—(1) *Amount.* One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klebsiella* spp., and *Hemophilus* spp.

(ii) *Limitations.* Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount.* One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

(3) *Amount.* One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer directly by mouth or crush and dissolve in

water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992]

§ 520.446 Clindamycin hydrochloride capsules.

(a) *Specifications.* Each capsule contains the equivalent of 25, 75, or 150 milligrams of clindamycin as the hydrated hydrochloride salt.

(b) *Sponsor.* No 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use.* For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*.

(3) *Limitations.* Wound infections, abscesses, and dental infections: Do not use more than 4 days if no improvement of acute infection is observed. Osteomyelitis: Do not use for more than 28 consecutive days if no improvement is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, and horses. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 23341, June 6, 1984, as amended at 51 FR 34960, Oct. 1, 1986; 54 FR 47767, Nov. 17, 1989]